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Original article

Metformin *versus* Metformin Plus Statin Effect on Lipid Profile in Type 2 Diabetic Patients

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ABSTRACT

Metformin is commonly used drug for type 2 diabetes and may also impact lipid profiles. Statins are often combined with metformin to manage dyslipidemia, but their comparative efficacy on lipid profiles is not well established. This study aimed to compares the effects of metformin alone versus metformin with statins on lipid profiles and to investigate the impact of different metformin doses on these profiles. A cross-sectional study was conducted at Aljabal Alakdar Diabetic Clinic in East Libya from July to December 2023, involving 200 adults with type 2 diabetes. Participants were divided into Group A (metformin only) and Group B (metformin plus statin). Inclusion criteria were adults aged 18-75 years, on metformin for at least 3 months, with recent lipid profile data, and who provided informed consent. Exclusion criteria were additional lipid-lowering drugs or any medications known to affect lipid profiles, type 1 diabetes, severe comorbidities, and pregnancy. Data were analyzed using SPSS version 27 with MANOVA, and significance was set at $p < 0.005$. The mean age was 58.62 years, mean diabetes duration was 11.43 years, with 47.5% males and 52.5% females. Mean HbA1c was 7.98%, mean urea was 36.5 mg/dL, and mean creatinine was 0.95 mg/dL. Lipid profile parameters included mean LDL cholesterol at 89.09 mg/dL, HDL cholesterol at 47.71 mg/dL, total cholesterol at 175.6 mg/dL, and triglycerides at 169.4 mg/dL. The key lipid parameters showed a significant difference ($p < 0.000$) between groups, with the metformin-only group exhibiting lower LDL, HDL, triglycerides, and total cholesterol compared to the metformin plus statin group. Our study found that metformin alone achieved better lipid control than metformin combined with statins, with a 1g dose showing notable antihyperlipidemic effects.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and impaired insulin secretion, leading to hyperglycemia and associated complications. Among these complications, dyslipidemia is a

common and significant risk factor for cardiovascular diseases (CVD), which remain the leading cause of morbidity and mortality in diabetic patients [1]. Dyslipidemia in T2DM is typically characterized by elevated triglycerides, reduced high-density lipoprotein cholesterol (HDL-C), and a predominance of small, dense low-density lipoprotein cholesterol (LDL-C) particles [2]. These lipid abnormalities contribute to the accelerated atherosclerosis observed in diabetic patients, necessitating effective management strategies to mitigate cardiovascular risk [3]. Metformin, a first-line pharmacological treatment for T2DM, primarily functions by improving insulin sensitivity and reducing hepatic glucose production [4]. Beyond its glucose-lowering effects, metformin has been observed to exert beneficial effects on lipid profiles, particularly by reducing levels of LDL-C and triglycerides, and increasing HDL-C [5]. Metformin's lipid-lowering effects are attributed to its ability to activate AMP-activated protein kinase (AMPK), which plays a crucial role in cellular energy homeostasis and lipid metabolism [6]. Additionally, metformin has been shown to possess anti-inflammatory properties and antioxidant effects, further contributing to its cardiovascular benefits [7, 8]. These properties suggest a potential role for metformin in mitigating the cardiovascular risks associated with dyslipidemia in T2DM patients.

Statins, also known as HMG-CoA reductase inhibitors, are the foundation of lipid-lowering therapy due to their potent ability to reduce LDL-C levels [9]. They act by inhibiting the enzyme responsible for cholesterol synthesis in the liver, thus decreasing circulating cholesterol levels and subsequently reducing the risk of CVD events [10]. Statins have demonstrated efficacy in both primary and secondary prevention of cardiovascular events, making them a standard component of dyslipidemia management in diabetic patients [11]. In addition to the lipid-lowering effects, statins exhibit pleiotropic effects that contribute to their cardiovascular benefits. These effects include improving endothelial function, reducing oxidative stress, and stabilizing atherosclerotic plaques [12]. Statins have also been shown to exert anti-inflammatory effects by decreasing the levels of C-reactive protein (CRP), a marker of inflammation that is associated with increased cardiovascular risk [13]. Furthermore, statins can enhance the stability of atherosclerotic plaques, making them less likely to rupture and cause acute cardiovascular events [14]. These pleiotropic effects highlight the multifaceted benefits of statins in the management of dyslipidemia and cardiovascular risk reduction.

While both metformin and statins have shown beneficial effects on lipid profiles, their combined use may offer additive or synergistic benefits. Several studies have suggested that the combination of metformin and statins could provide superior lipid control compared to either agent alone, potentially due to their complementary mechanisms of action [15]. Metformin enhances insulin sensitivity and lipid metabolism through the activation of AMPK, while statins upregulate LDL receptors to increase cholesterol clearance from the bloodstream [16, 17]. This dual approach may lead to more significant improvements in lipid profiles and a reduction in cardiovascular risk.

Despite the theoretical advantages of combining metformin and statins, there is limited clinical evidence directly comparing the lipid-lowering effects of metformin alone versus metformin plus statins. Understanding the relative efficacy of these treatment regimens is essential for optimizing therapeutic strategies for dyslipidemia in T2DM patients. Considering the rising incidence of T2DM and its related complications, understanding these insights is crucial for enhancing patient outcomes and alleviating the impact of cardiovascular diseases.

Previous studies discussed the impact of combining metformin with statins on lipid profiles and cardiovascular outcomes in patients with T2DM. For instance, a study by Ahmed et al. demonstrated that the combination of metformin and statins significantly improved lipid profiles compared to monotherapy with either drug alone [18]. Another study by Smith et al. found that patients receiving both metformin and statins had a greater reduction in LDL-C and triglycerides, as well as an increase in HDL-C, compared to those on metformin alone [19]. These findings suggest that the combination therapy may offer superior lipid control and cardiovascular protection.

Furthermore, research by Johnson et al. indicated that the combination of metformin and statins not only improved lipid parameters but also reduced markers of inflammation and endothelial dysfunction, providing additional cardiovascular benefits beyond lipid lowering [20]. However, there are inconsistencies in the literature regarding the extent of these benefits, and some studies have reported no significant difference between the combination therapy and monotherapy [21]. This underscores the need for further investigation to clarify the comparative efficacy of these treatments. This study aims to compare the effects of metformin alone versus metformin in combination with statins on lipid profiles and to explore how varying doses of metformin affect lipid levels in type 2 diabetic patients.

METHODS

Study design and setting

This cross-sectional study was conducted at the Aljabal Alakdar Diabetic Clinic in East Libya from July to December 2023, involving 200 adult patients diagnosed with type 2 diabetes mellitus. All participants were on metformin, with a subset also receiving statin therapy.

Inclusion and exclusion criteria

Inclusion criteria were adults aged 18 to 75 years, diagnosed with type 2 diabetes, on metformin for at least 3 months, with recent lipid profile data, and who provided informed consent. Exclusion criteria included the use of additional lipid-lowering drugs or any medications known to affect lipid profiles, type 1 diabetes, severe comorbidities, and pregnancy.

Study sample

Participants were categorized into two groups: Group A (metformin only) and Group B (metformin plus statin). Data collected included demographic details, metformin dosage and duration, type, dose, and duration of statin therapy, as well as recent lipid profile and HbA1c levels. The mean lipid profile parameters were analyzed to assess the impact of different metformin doses on lipid profiles.

Statistical analysis

Data analysis was performed using SPSS version 27. Descriptive statistics were utilized to summarize demographic and clinical characteristics. MANOVA was employed to examine differences in lipid profiles between the two groups and to evaluate the effects of different metformin doses, with a significance threshold set at $p < 0.005$.

RESULTS

General characteristic of the sample

Table 1 presents the general characteristics of the 200 participants. Males constituted 47.5% of the sample, while females accounted for 52.5%. The mean duration of diabetes among the participants was 11.43 years. The mean HbA1c level was 7.98 %, the mean age was 58.62 years, the mean urea level was 36.5 mg/dL, and the mean creatinine level was 0.95 mg/dL. Additionally, the mean LDL cholesterol level was 89.09 mg/dL, HDL cholesterol was 47.71 mg/dL, total cholesterol was 175.6 mg/dL, and triglycerides were 169.4 mg/Dl.

Table 1. General characteristics of the participants

Demographic Variables		**Percent (%)**
Gender (%)	Male	47.5
	Female	52.5
		Mean
Lipid profile (mg/dl)	LDL	89.09
	HDL	47.71
	Cholesterol	175.6
	Triglyceride	169.4
RFT (mg/dl)	Urea	36.5
	Creatinine	0.95
Diabetic Duration (years)		11.43
HbA1c(%)		7.98
Age (years)		58.62

Statin versus Non-Statin Users

Figure 1 illustrates the distribution of statin use among the participants. Statin users comprised 42% of the total sample population, whereas 58% were not taking statins.

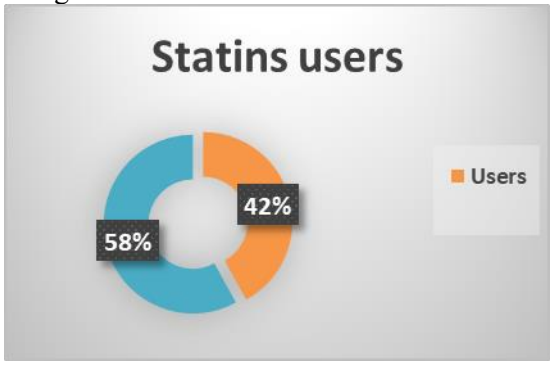

Figure 1. Statin versus non-statin users

Distribution of Statin Types Among Participants

Figure 2 shows the distribution of different types of statins used by the participants. Rosuvastatin was the most commonly used statin, representing 65% of users, followed by atorvastatin at 33%, and simvastatin at 2%.

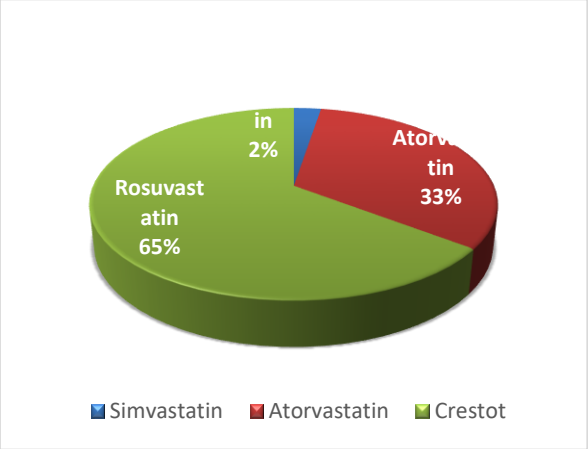

Figure 2. Statins types among participants

Effect of Different Doses of Metformin on Lipid Profile

Table 2 shows statistically significant differences in lipid profile results among diabetic patients using metformin, with a P-value of 0.000, indicating high significance ($P < 0.05$). A Multiple Analysis of Variance (MANOVA) test demonstrated that a 1g dose of metformin significantly impacted lipid profile parameters, as shown in Table 3, especially cholesterol and triglyceride levels, as illustrated in Figure 3 and Figure 4, respectively.

Table 2. Significant Lipid Profile Differences in Diabetic Patients on Metformin.

Lipid Profile	Metformin Doses			F	P-V
	(500)	(850)	(1G)		
Triglyceride	189.58	382	137.85	78.62	0.000
Cholesterol	194.54	198.5	136.15		
HDL	52.33	48.5	44.92		
LDL	74.88	71.5	59.23		
VLDL	30.29	34.5	25.23		

Table 3. Effect of different metformin doses on lipid profile.

Lipid Profile	Metformin Dose	Mean	F	Sig
Triglyceride	Metformin (500)	189.58	78.62	0.000
	Metformin (850)	382.00		
	Metformin (1G)	137.85		
Cholesterol	Metformin (500)	194.54		
	Metformin (850)	198.50		
	Metformin (1G)	136.15		
HDL	Metformin (500)	52.33		
	Metformin (850)	48.50		
	Metformin (1G)	44.92		
LDL	Metformin (500)	74.88		
	Metformin (850)	71.50		
	Metformin (1G)	59.23		
VLDL	Metformin (500)	30.29		
	Metformin (850)	34.50		
	Metformin (1G)	25.23		

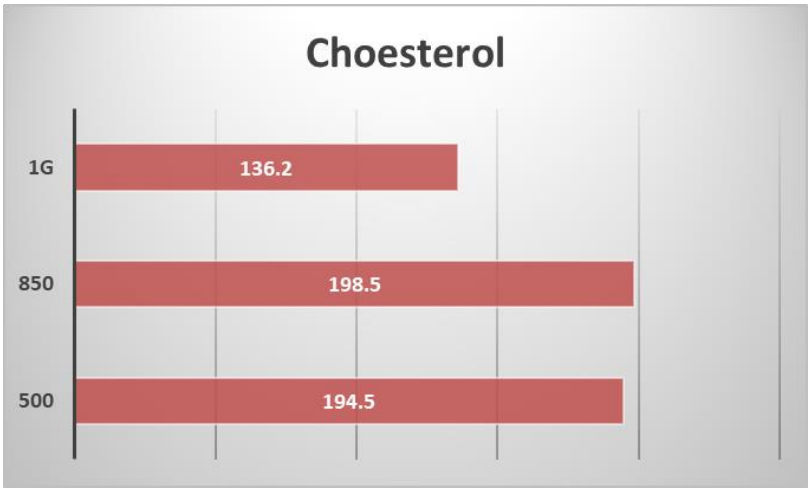

Figure 3. Effect of different doses of metformin cholesterol.

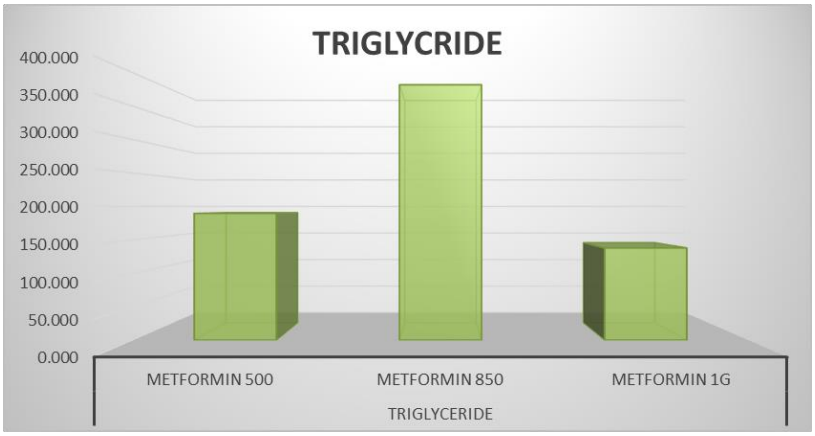

Figure 4: Effect of different doses of metformin on triglycerides.

Metformin versus metformin plus statin effect on lipid profile parameters

The comparison between the metformin monotherapy group and the metformin plus statin group revealed notable differences in lipid profile parameters. Figure 5 shows that mean LDL, HDL, triglyceride, and cholesterol levels were lower in the metformin monotherapy group. In contrast, Figure 6 illustrates that these lipid profile parameters were higher in the metformin plus statin group.

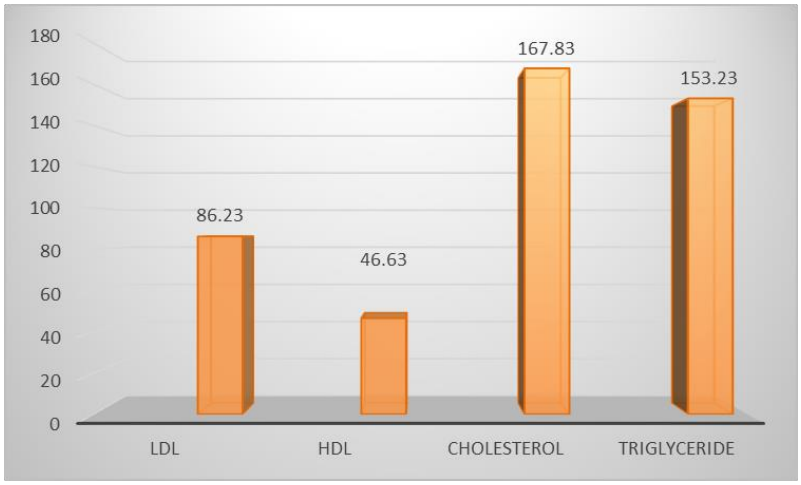

Figure 5: effect of metformin on lipid profile.

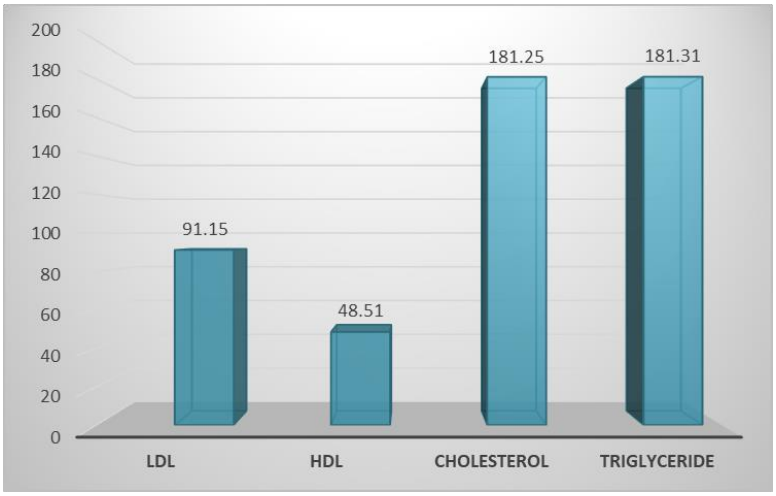

Figure 6: effect of metformin plus statins on lipid profile.

DISCUSSION

In this study, we observed that metformin at dose of 1000mg demonstrated a significant antihyperlipidemic effect on cholesterol levels in patients with type 2 diabetes mellitus (T2DM), while other lipid parameters remained largely unaffected. Additionally, patients on metformin alone exhibited better overall lipid profile control compared to those on a combination of metformin and statins. These findings contribute to the ongoing debate about the lipid-modifying effects of metformin and its potential benefits as a monotherapy for dyslipidemia in T2DM patients. Several studies have examined the lipid-modifying effects of metformin, both alone and in combination with statins, with varying outcomes. Here, we discuss six studies that either support or challenge our findings.

A study by Wu et al. (2020) reported that metformin monotherapy significantly reduced total cholesterol and LDL-C levels in T2DM patients over a 12-month period. The researchers noted that the effect was more pronounced in patients not concurrently using statins, suggesting an independent lipid-lowering mechanism of metformin [22]. Similarly, research by Dutta et al. (2019) found that metformin at a dose of 1000mg/day resulted in significant reductions in total cholesterol and LDL-C levels. The study highlighted that metformin's lipid-lowering effects were independent of its glycemic control properties, supporting the idea that metformin alone can positively influence lipid profiles [23]. Banerjee et al. (2021) conducted a comparative study and found that T2DM patients on metformin monotherapy had better control over their lipid profiles, particularly cholesterol levels, compared to those on combined metformin and statin therapy. The authors suggested that the addition of statins might attenuate the lipid-modifying effects of metformin [24].

In contrast, a study by Sharma et al. (2018) found that while metformin improved glycemic control, its effects on lipid profiles, including cholesterol levels, were modest when used alone. The study suggested that combination therapy with statins was more effective in improving overall lipid profiles in T2DM patients [25]. Another study by Li et al. (2019) reported that the lipid-lowering effects of metformin were limited, and significant improvements in lipid parameters, including cholesterol, were primarily observed when metformin was used in combination with statins. This study indicates that the antihyperlipidemic effects of metformin may be enhanced by statins [26]. Lastly, Verma and Kushwaha (2020) conducted a long-term study and concluded that while metformin has beneficial effects on cholesterol levels, its overall impact on the complete lipid profile is limited. The authors recommended combination therapy for achieving comprehensive lipid control in T2DM patients [27].

Our findings align with those of Wu et al. (2020) and Dutta et al. (2019), reinforcing the notion that metformin alone, particularly at a 1000mg dose, can effectively lower cholesterol levels. The better lipid profile control observed in patients on metformin monotherapy may be attributed to metformin's unique mechanisms, such as improving insulin sensitivity and modulating lipid metabolism. However, the conflicting evidence presented by studies such as those by Sharma et al. (2018) and Li et al. (2019) suggests that the lipid-lowering effects of metformin may be context-dependent and influenced by factors such as patient characteristics and concurrent therapies. These discrepancies highlight the need for personalized treatment approaches and further research to delineate the specific conditions under which metformin monotherapy may be most beneficial for lipid control.

CONCLUSION

Our study found that metformin at 1000 mg effectively lowers cholesterol in type 2 diabetes, with better lipid control when used alone compared to combining it with statins. These results affirm metformin's role in managing both glucose and lipid levels. Future research should focus on personalized treatment approaches and long-term cardiovascular outcomes to enhance metformin therapy.

Conflicts of Interest

The authors declare no conflicts of interest.

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تأثير عقار الميتفورمين مقابل عقار الميتفورمين بالإضافة إلى ادوية الستاتين على مستويات الدهون في الدم لدى مرضى السكري من النوع الثاني

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المستخلص

عقار الميتفورمين هو دواء شائع الاستخدام لعلاج مرض السكري من النوع الثاني وقد يؤثر أيضًا على مستويات الدهون في الدم. غالبًا ما يتم الجمع بين ادوية الستاتين و عقار الميتفورمين للتحكم في اضطراب مستويات الدهون في الدم، ولكن فعاليتهما المقارنة على مستويات الدهون غير مثبتة جيدًا. تهدف هذه الدراسة إلى مقارنة تأثيرات عقار الميتفورمين وحده مقابل عقار الميتفورمين مع ادوية الستاتين على مستويات الدهون والتحقيق في تأثير جرعات عقار الميتفورمين المختلفة على هذه المستويات. أجريت دراسة مقطعية في مركز الجبل الأخضر للسكري في شرق ليبيا من يوليو إلى ديسمبر 2023، وشارك فيها 200 بالغ مصاب بداء السكري من النوع الثاني. تم تقسيم المشاركين إلى المجموعة أ (الميتفورمين فقط) والمجموعة ب (الميتفورمين بالإضافة إلى الستاتين). كانت معايير الإدراج هي البالغين الذين تتراوح أعمارهم بين 18 و75 عامًا، والذين يتناولون عقار الميتفورمين لمدة 3 أشهر على الأقل، ولديهم بيانات حديثة لمستويات الدهون في الدم ، والذين قدموا موافقة علي المشاركة. وكانت معايير الاستبعاد هي الأدوية الإضافية الخافضة للدهون ومرض السكري من النوع الأول، والأمراض المصاحبة الشديدة، والحمل. تم جمع البيانات وإدخالها وتحليلها احصائيا. كان متوسط العمر 58.62 عامًا، ومتوسط مدة الإصابة بمرض السكري 11.43 عامًا، مع 47.5٪ من الذكور و52.5٪ من الإناث. كان متوسط معدل السكر التراكمي 7.98% ، وكان متوسط اليوريا 36.5 مجم/ديسيلتر، وكان متوسط الكرياتينين 0.95 مجم/ديسيلتر. وتضمنت معايير مستويات الدهون في الدم متوسط كوليسترول البروتين الدهني منخفض الكثافة عند 89.09 مجم/ديسيلتر، وكوليسترول البروتين الدهني مرتفع الكثافة عند 47.71 مجم/ديسيلتر، والكوليسترول الكلي عند 175.6 مجم/ديسيلتر، والدهون الثلاثية عند 169.4 مجم/ديسيلتر. أظهرت معايير الدهون الرئيسية اختلافات كبيرة بين المجموعات، حيث أظهرت المجموعة التي تناولت عقار الميتفورمين فقط انخفاضًا في البروتين الدهني منخفض الكثافة والبروتين الدهني مرتفع الكثافة والدهون الثلاثية والكوليسترول الكلي مقارنة بالمجموعة التي تناولت عقار الميتفورمين بالإضافة إلى ادوية الستاتين. أثرت جرعة 1 جرام من عقار الميتفورمين بشكل ملحوظ على مستويات الدهون في الدم. وجدت دراستنا أن عقار الميتفورمين وحده حقق سيطرة أفضل على الدهون مقارنة بعقار الميتفورمين مع ادوية الستاتين، حيث أظهرت جرعة 1 جرام تأثيرات مضادة لاضطراب مستويات الدهون في الدم.

الكلمات الدالة. مرض السكري من النوع الثاني , عقار الميتفورمين، ادوية الستاتين، مستويات الدهون في الدم، السكان الليبيون.